

MAY - 9 2003

K030680

510(k) Summary of
Safety and Effectiveness

Submitter:

- SPSmedical Supply Corp.
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Rush, NY 14543 U.S.A.
Phone: (585)-359-0130 Fax: (585)-359-0167
- Establishment FDA Registration No.: 1319130
- Date Summary was Prepared April 17, 2003
- Gary J. Socola
Printed name of person submitting for 510(k)
- Gary J. Socola
Signature of person submitting for 510(k)
- Director of Quality Assurance
Title of person submitting for 510(k)

Device Name and Classification

Trade Name:	SPSmedical Gas Plasma Chemical Indicator
Classification Name:	Physical/Chemical Sterilization Process Indicator
Common Name:	Chemical Indicator
Device Classification:	General Hospital - Class II, Regulation Number 880.2800
Product Code:	80JOJ
Predicate Device:	Advanced Sterilization Products (ASP) Gas Plasma Indicator Strip (K921910).

Device Description:

The SPSmedical Gas Plasma Chemical Indicators are process indicators used to verify exposure to vapor hydrogen peroxide in the STERRAD[®] 100, STERRAD[®] 100S and STERRAD[®] 50 sterilization processes. They provide a visual indication to help distinguish between processed and unprocessed items

Intended Use:

The SPSmedical Gas Plasma Chemical Indicators are indicated for use as process indicators to verify exposure to vapor hydrogen peroxide in the STERRAD[®] 100, STERRAD[®] 100S and STERRAD[®] 50 sterilization processes. They are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items.

Technical Characteristics:

The SPSmedical Gas Plasma Chemical Indicators are process indicators used to verify exposure to vapor hydrogen peroxide in the STERRAD[®] 100, STERRAD[®] 100S and STERRAD[®] 50 sterilization processes. The indicators provide a visual indication that hydrogen peroxide (H₂O₂), an essential ingredient in the STERRAD[®] sterilization process has been introduced into the sterilizer's chamber. There are two indicators types. The first indicator changes from a YELLOW beginning color to a BLUE signal color and the second changes from a RED beginning color to a BLUE signal color. SPSmedical is claiming substantial equivalence for its SPSmedical gas plasma chemical indicators to the ASP chemical indicator strip based on test data taken during comparison studies. Testing has demonstrated that the SPSmedical gas plasma chemical indicators perform consistently with equivalent results to that of the predicate ASP indicator strip. Both indicate exposure to the STERRAD[®] sterilization process. The SPSmedical gas plasma chemical indicators are also comparable to other commercially available indicators currently cleared by the FDA.

Comparison of the SPSmedical Chemical Indicators to the Predicate

ELEMENT	NEW DEVICE	PREDICATE
Intended use	Process Indicator	Process Indicator
Device design	Strip, Label, Card	Strip
Indicator agent	Indicator Ink	Indicator Ink
Sterilization method	STERRAD [®] (H ₂ O ₂)	STERRAD [®] (H ₂ O ₂)
Initial Color/Endpoint Color	Yellow/Blue or Red/Blue	Red/Yellow
Substrate	Synthetic Paper	Synthetic Paper
Shelf-life	2 years	1 year

Non-Clinical Testing:

During performance testing with the SPSmedical Gas Plasma Chemical Indicators between 3,000-4,000 indicators were tested from 13 separate lots of indicators containing multiple lots of substrates and indicator inks. Multiple lots of the predicate ASP indicator strips and tape were also included during the various testing.

Indicator samples were placed within an Advanced Sterilization Products (ASP) STERRAD® 100 GMP test vessel along with the predicate ASP indicator strip product. The indicators were then subjected to incomplete and complete reaction cycle conditions. In the incomplete cycle the H_2O_2 concentration was adjusted to 120 μL , resulting in 0.5 mg/L of H_2O_2 . This level is significantly less than the normal concentration of 1440 μL of the 58% H_2O_2 solution which results in the typical concentration of 6.0 mg/L of H_2O_2 . In the complete reaction cycle the H_2O_2 concentration was adjusted to be one half (720 μL) of the nominal concentration of 1440 μL of the 58% H_2O_2 solution resulting in 3.0 mg/L of H_2O_2 . All incomplete and complete reaction cycles were allowed to run their normal processing parameters with the only exception being the reduced H_2O_2 concentrations which were injected into the STERRAD® 100 GMP test vessel. The incomplete and complete reaction cycles were repeated a total of 3 times. Indicators were observed for proper color change and results were recorded.

All SPSmedical gas plasma indicator samples processed for the incomplete reaction cycles showed "No change or a change that is markedly different from the change occurring after exposure" to the relevant full plasma sterilization process cycle (a color other than BLUE) and all indicator samples processed in the complete reaction cycles showed "A full signal color change to BLUE". Throughout the various testing the SPSmedical gas plasma chemical indicators and the ASP chemical indicator strips reacted similarly in all test configurations.

Recommended Storage Conditions

Store in a cool, dry place (15-30°C), away from any alkaline chemicals and acids.

Interfering Substances or Conditions

The SPSmedical gas plasma chemical indicators were tested for the effects of acid and base. Testing verified that the indicators in their *unprocessed* form are not sensitive to an acidic or basic environment. Testing verified that the indicators in their *processed* form are sensitive to an acidic or basic environment. The instructions for use include a precaution to store the indicators away from any alkaline chemicals and acids.

Steam/EO Gas Exposure

Indicators printed on Tyvek and polypropylene were exposed to a steam sterilization cycle of 132°C for 4 minutes exposure time and in a 100% EO Gas sterilizer running at 600mg/l for 60 minutes exposure with 70%RH. The indicators were unaffected by the EO Gas process.

The indicators printed on polypropylene shrunk slightly but were otherwise unaffected in the steam process. The indicators printed on Tyvek were grossly deformed in the steam process.

Stability

Light stability was verified over a 2 1/2 month period on indicators which achieved a complete signal color change when *processed* in a STERRAD[®] Gas Plasma cycle with a H₂O₂ concentration of 6.0 mg/L and on *unprocessed* indicators. Both were subjected to natural and artificial light sources. Results verified the stability of the product to retain their initial indicator color and their post processing signal color during this period. Furthermore, the indicators were not affected by, nor did they experience any substantial fading when subjected to natural or artificial light sources in either their *unprocessed* or *processed* form.

Shelf life

The shelf life of the SPSmedical Plasma Chemical Indicators shall be 2 years from the date of manufacture, when stored in a cool, dry place (15-30°C). Indicators from unopened and opened packages were tested for proper color change results. Five and one-half month interim results verified that all indicators turned to their appropriate signal color when subjected to a STERRAD[®] cycle with an injection volume of 720 µL of the 58% H₂O₂ solution giving a concentration 3.0 mg/L of H₂O₂. A two year stability testing study is ongoing.

Biocompatibility

SPSmedical Gas Plasma Chemical Indicators are printed using nontoxic inks and coatings that will not alter the chemical composition of the products being sterilized and are safe for human contact. The synthetic paper used in the manufacturing of the SPSmedical gas plasma chemical indicator strip complies with 21 CFR 177.1520.

Conclusion

Supportive data has demonstrated that the SPSmedical gas plasma chemical indicators are equivalent to the predicate device. Throughout the various testing, the SPSmedical gas plasma chemical indicators and the ASP chemical indicator strips reacted similarly in all test configurations. The SPSmedical gas plasma chemical indicators have the same intended use and characteristics as the ASP strip. The SPSmedical and ASP products are comprised of synthetic paper materials and are printed with indicator inks which provide a visual indication after being exposed to vapor hydrogen peroxide in the STERRAD[®] sterilization process. SPSmedical believes that the SPSmedical gas plasma chemical indicators are substantially equivalent to the predicate device because it has the same intended use, technical characteristics and performance. All SPSmedical gas plasma chemical indicators are effective and reliable, single use devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SPS Medical Supply Company
Mr. Ned Devine
Responsible Third Party official
ENTELA, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K030680

Trade/Device Name: SPSmedical Gas Plasma Chemical Indicator
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: April 25, 2003
Received: April 28, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS for USE STATEMENT

Applicant: SPSmedical Supply Corp.510(k) Number (if known): K030680Device Name: SPSmedical Gas Plasma Chemical Indicator

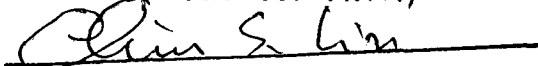
Indications For Use:

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NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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